UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

PR Notice 83-4

NOTICE TO MANUFACTURERS, FORMULATORS, DISTRIBUTORS, APPLICANTS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticides

SUBJECT: Interim Procedures For Satisfying Registration Data Requirements Under Recent Court Decisions

The United States Environmental Protection Agency ("EPA" or "Agency") is issuing this PR Notice to announce an interim procedure, called the Owner Submission Method, by which applicants for registration or amended registration under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, ("FIFRA") (7 U.S.C. §§136-136y) may satisfy the statutory requirement to provide data to support their applications. Specifically, the Owner Submission Method requires applicants to support applications with a minimum set of data, as described in EPA's regulations and guidelines which set forth the data requirements for registration. In addition, the procedures make it possible for an applicant to satisfy those registration data requirements either by submitting or citing his own data or by citing data submitted by others who have given the applicant permission to rely on their data. Under these procedures, the Agency will remain free to evaluate all relevant data in its files in deciding, on risk/benefit grounds, whether to approve or deny any application for registration of a pesticide.

These interim procedures respond to the rulings in two recent court cases: National Agricultural Chemical Association v. U.S. Environmental Protection Agency, No. 79-2063 (D.D.C., Jan. 20, 1983)("NACA"); and Monsanto Co. v. Acting Administrator, No. 79-366C(1) (E.D. Mo., May 9, 1983) ("Monsanto"). The procedures established by this PR Notice take effect on June 30, 1983, and will remain in effect until the Agency promulgates final, effective rules governing the requirements for data supporting registration at the completion of the pending rulemaking proceeding to modify 40 C.F.R. §§162.9-1 through 162.9-8. This PR Notice is provided directly to all registrants and registration applicants and to all individuals and groups who have identified an interest in these matters. Additional copies will be provided to any person upon request.

Persons with pending applications for registration actions who desire to pursue those applications must resubmit or modify them as necessary to comply with this Notice. The PROCEDURES follow the INTRODUCTION.

INTRODUCTION

I. Background

The Agency is responsible for regulating the sale, distribution, and use of pesticides under FIFRA. With certain minor exceptions, FIFRA requires that all pesticides must be registered by EPA before they may be sold or distributed in commerce. To obtain a registration, an applicant is required, among other things, to submit or cite data which the Agency may consider in support of the application. FIFRA §3(c)(1)(D) states that the application must contain "a full description of the tests made and the results thereof . . . or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator . . . ." Section 3(c)(1)(D), however imposes certain limitations on an applicant's right to cite, without permission, data submitted by others.

EPA originally interpreted FIFRA to require an applicant to cite in support of his application any item of data which the Agency might review or use in deciding whether to register a product, i.e., all relevant data in the Agency's files. Thus, until recently, EPA's registration program operated under the so-called "cite-all" regulations, 40 C.F.R. §162.9-1 through § 162.9-8, published in 1979. These regulations required applicants to cite in their applications all relevant data previously submitted to EPA, regardless of the amount of their own data they provided with their applications.

The January 1983 NACA decision essentially rejected EPA's interpretation and held the 1979 regulations invalid insofar as they required an applicant to cite every study in the Agency's files relevant to the applicant's product. The district court therefore enjoined EPA from requiring applicants to submit or cite more data than required to meet "the statutory criteria for registration."

EPA's response to the NACA decision was (1) to discontinue requiring applicants to follow the "cite-all" regulations, (2) to allow applicants who did not wish to wait until new procedures were in place to voluntarily follow the "cite-all" regulations, and (3) to start development of alternative procedures (embodied in this PR Notice) complying with the NACA decision. While this PR Notice was under development, the Monsanto decision was announced; this decision enjoined use of data in support of applications without the original submitter's permission. The

Agency halted registration under the "voluntary cite-all" approach as barred by Monsanto except in the very few cases where EPA could determine that only the applicant had submitted any relevant data.

EPA recognizes that the procedures established by this PR Notice directly affect the rights and obligations of applicants and data submitters. Ordinarily, the Agency would not establish such procedures without first seeking public comment using the external review procedures prescribed by FIFRA and the Administrative Procedure Act. The combination of the NACA and Monsanto decisions, however, has brought the registration process to a virtual halt. In the absence of a clear set of procedures to replace the cite-all regulations, EPA could not inform applicants of the information they were required to provide in order to be registered, nor could the Agency efficiently determine whether an applicant had satisfied the statutory requirements for registration. The Agency's inability to issue new registrations has prevented applicants from obtaining approval to market new, potentially safer and more effective products.

The Agency currently has underway a rulemaking to establish a system for supporting pesticide registrations with the required data and to implement the provisions of FIFRA §3(c)(1)(D). The proposed regulations were published for public comment on December 27, 1982 (47 F.R. 57,635) after the United States Court of Appeals invalidated the Agency's existing data compensation rules on procedural grounds. Mobay v. Gorsuch, 682 F.2d 419 (3d Cir. 1982). (The Court of Appeals, however, left the previous rules in effect during the period required for a replacement rulemaking.) The proposal requested comment on several issues, including alternatives to the cite-all approach. Following the NACA decision invalidating the cite-all regulations, EPA extended the deadline for filing public comments until May 6, 1983. 48 F.R. 13,196 (Mar. 30, 1983). In view of the potentially long delays -- up to a year -- involved in promulgating final regulations which are designed to establish registration procedures, the Agency has determined that it should issue interim procedures through a PR Notice in order to respond promptly to the requirements of the NACA and Monsanto decisions.

In arriving at the particular procedures described in this Notice, the Agency invited comments from several industry trade associations and an environmental group that had shown interest in data compensation issues. In addition, the Agency distributed copies of earlier drafts of these procedures to numerous individuals who requested information concerning EPA's response to the NACA decision.

The procedures established here will be in effect only temporarily, until such time as the Agency can promulgate final regulations. The final regulations may differ from this interim procedure. 1/ Comments on these interim procedures will be explicitly solicited and evaluated during the pending rule-making proceeding and will be considered in preparing the final rule.

II. The Statutory Scheme

After reviewing the statute in detail in light of the NACA and Monsanto decisions, the Agency has concluded that there is an important distinction in the statute between (1) EPA review of submitted or cited data to determine whether the applicant has satisfied the requirements of FIFRA that specify how an application must be supported, and (2) EPA review of data (whether or not submitted or cited by the applicant) to determine whether to approve a properly supported application. In the first type of review, EPA must decide whether the application is complete, i.e., whether the materials required to be submitted with the application meet the requirements established pursuant to §3(c)(1) and §3(c)(2)(A). As a part of that process, the Agency must ensure that the applicant has not violated any of the economic rights of other data submitters under FIFRA nor violated the recent Monsanto decision.

Once it is clear that an applicant has submitted a complete and properly supported application and therefore meets the criterion for registration described in §3(c)(5)(B), EPA will undertake the second step of its review. In this second step, EPA must decide whether the product meets the statutory criteria in either FIFRA §3(c)(5)(C) and (D) or §3(c)(7)(A) or (B) and,

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1/ In particular, the Agency has been asked to adopt a procedure by which applicants can satisfy a set of minimum data requirements not only by the methods outlined in this PR Notice but also by citing studies without the data submitters' permission. Such an applicant would be required to offer to pay compensation for the right to rely on the data, to the extent required by section 3(c)(1)(D). Such an approach would have been impractical to implement on a temporary basis in this interim procedure. Moreover, it would be prohibited by the district court's injunction in the Monsanto case. If the Monsanto injunction is stayed or overturned, however, the Agency will address this approach to meeting the Agency's registration data requirements in the rulemaking process.

particularly, whether it may be registered on risk/benefit grounds. In making this risk/benefit determination, the public interest requires EPA to take into account each item of data that would contribute to a well-reasoned decision. Nothing in either FIFRA or the recent court decisions prohibits EPA's evaluation of all relevant data at this second stage.

EPA's review of applications (1) for data completeness and (2) on risk/benefit grounds is governed by §§3(c)(5) and 3(c)(7). Section 3(c)(5)(B) governs the first step in EPA's review of materials submitted in support of applications by stating that EPA may register a pesticide only if "its labeling and other material required to be submitted comply with the requirements of the Act." The "labeling and other material required to be submitted" consist of the various items listed in §3(c)(1); the Act requires no other submissions by applicants. With respect to data, §3(c)(1)(D) states that the application must contain "a full description of the tests made and the results thereof . . . , or alternatively a citation to data . . . that previously had been submitted to the Administrator and that the Administrator may consider" under the restrictions of §3(c)(1)(D)(i)-(ii).

The kind and amount of data an applicant must submit or cite to obtain a registration is governed by §3(c)(2)(A). That section directs EPA to "publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide . . ." The most recent version of the §3(c)(2)(A) guidelines are found in proposed 40 C.F.R. Part 158, 47 FR 53,192 (Nov. 24, 1982). 2/ Thus, §3(c)(2)(A) (and EPA's implementing guidelines) define how much data an applicant must submit in support of his application; §3(c)(1)(D) describes how an applicant may properly assemble that required data package (by generating his own set of data, citing others' data with permission, or relying on the mandatory licensing provisions 3/ of §3(c)(1)(D)(ii)

2/ These guidelines (as did earlier versions) describe what tests must be conducted, and to some extent how they should be conducted in order to produce usable results. They do not specify what specific results the testing must produce, and neither EPA nor the regulated industry has asserted that they should.

3/ As explained later in this Notice, the Monsanto decision, at this time, precludes use of mandatory licensing to satisfy data requirements.

and (iii)); and §3(c)(5)(B) states that an application may not be approved unless these requirements have been fulfilled. 4/ This process fully defines the first step of EPA's review of applications.

Sections 3(c)(5) and 3(c)(7) also require the Agency to make a second type of determination, a determination of the safety of the product, i.e., that use of the product will not cause unreasonable adverse effects on the environment (§3(c)(5)(C) and (D)) or that use of the product will not significantly increase the risk of unreasonable adverse effects on the environment (§3(c)(7)(A) and (B)). 5/ For this second step of Agency review, nothing in FIFRA limits the range of data to which EPA may refer in making these risk/benefit decisions. To the contrary, Congress contemplated that EPA would be free to look beyond the data submitted by an applicant in evaluating the safety of a product. This intent is evident in the last sentence of FIFRA §3(c)(2)(A): "Except as provided by section 10, within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public the data called for in the registration statement, together with such other scientific information as he deems relevant to his decision." 6/

4/ The statutory criterion concerning data submission for conditional registration under FIFRA §3(c)(7)(A) or (B) is derived from the §3(c)(5)(B) criterion previously discussed: "[a]n applicant . . . shall submit such data as would be required to obtain registration of a similar pesticide under subsection (3)(c)(5)," except that certain data need not be submitted if other similar products have already been registered without submission of those data. Thus, the data required to be submitted by the applicant under §3(c)(7), as under §3(c)(5), are the data specified in the Agency's pesticide registration guidelines.

5/ FIFRA §2(bb) defines "unreasonable adverse effects on the environment" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." This definition clearly contemplates that the Agency will consider information which applicants are not required to provide, e.g. economic and social benefits of the use of a pesticide.

6/ Emphasis added. Although EPA implementation of disclosure pursuant to this section has been enjoined by the Monsanto decision, its use in interpreting congressional intent presumably is not affected by the court's order.

The NACA court apparently agreed with this distinction, concluding that:

> While it is commendable that the EPA does not intend to limit its inquiries to the data submitted by applicants, the plain language of the statute does not support the EPA's conclusion that the applicants are required to provide all the information the EPA would like to review.

NACA, slip opinion at 4.

The district court's decision in the Monsanto case, of course, alters the application of FIFRA §3(c)(1)(D) to the first step of EPA's review of data supporting registration applications. 7/ The court's April 12 and May 9, 1983, Orders held unconstitutional the portions of §3(c)(1)(D) that allow an applicant to support his application by citing another person's previously-submitted data without the data submitter's consent. The May 9 Order goes on to state that EPA is not prohibited

> from approving applications for pesticide registrations as permitted under §§3(c)(5) and 3(c)(7) of FIFRA in cases where the applicant has submitted to EPA, and relied solely upon, his own data to support his application for registration; provided that any applicant must either submit his own data, or cite his own previously submitted data, or cite data that appears in the public literature or cite the previously submitted data of another person with the prior written permission of such person, and further that EPA is precluded from considering or using any other data in support of any application for registration.

This ruling therefore prohibits an applicant from satisfying the requirement in §3(c)(1)(D) to provide the minimum set of data required by the guidelines by citing another's previously-submitted data without permission.

7/ The Monsanto decision also enjoined EPA from disclosing data under §3(c)(2)(A) and §10 of FIFRA; that part of the decision, however, is not pertinent here. EPA has appealed the Monsanto decision to the Supreme Court and expects shortly to apply to that Court for a stay of the district court's injunction. As described in the text, these procedures are consistent with the Monsanto opinion and injunction. If the injunction is stayed, EPA expects to supplement these procedures.

The ability of an applicant to obtain registration by citing another's data without the data submitter's permission was an overriding concern to the Monsanto court. In its Memorandum of Findings of Fact and Conclusions of Law (April 10, 1983), the court concluded with disapproval (at pp. 38-39) that "the 1978 amendments to FIFRA give Monsanto's competitors a free ride at Monsanto's expense." The court equated use of data "in support of [an] application" with use of data "for the benefit of [the] applicant," as contrasted with the presumably proper purpose of "determining the adequacy of the particular data submitted by an applicant." Finding 22, pp. 12-13. The court went on to find that: "[u]nless the relief sought by plaintiff is granted, defendant [EPA] will use plaintiff's test data . . . to grant these registrations as provided by section 3(c)(1)(D) of FIFRA." Finding 55, p. 27. Thus, the court's objective was to assure that applicants are not granted registrations unless they first produce as much information as EPA required from Monsanto or other prior registrants, either by submitting their own data, or by obtaining permission to cite earlier-submitted data. Moreover, so long as the applicant has produced his own data or obtained the data submitter's permission (and thus had not received an unconsented "free ride"), nothing in the court's decision would prohibit EPA from considering any relevant data to evaluate the risks of the applicant's product. 8/

Finally, the Agency rejects an interpretation of §3(c)(1)(D) urged by the National Agricultural Chemical Association (the "Association"). The Association recently asserted in a May 16, 1983, letter to the Director of the Office of Pesticides Programs that even if an applicant had submitted a complete set of its own valid data meeting the §3(c)(2)(A) guidelines, EPA would be constrained in its review of relevant data concerning the risks and benefits of the product and its ingredient. The

8/ This analysis thus differs from a position EPA earlier took, i.e., that a limit on unconsented consideration or use of data "in support of any application for registration" would affect EPA's use of data in deciding whether a properly-supported application may be approved on risk/benefit grounds. The analysis of the statute EPA has now conducted and set forth in this Notice shows that the position EPA took earlier is contrary to the decision in the NACA case and unsupported by FIFRA, properly interpreted.

Association argued that since the NACA decision allows a company to choose to satisfy the §3(c)(1)(D) data requirements by submitting its own data, it "follows a fortiori" from the language of § 3(c)(1)(D) that EPA must decide, based only on the data provided by the applicant, whether the product satisfies the §3(c)(5) or 3(c)(7) safety criteria for registration. Under the Association's approach, only if EPA concluded that the applicant's data independently demonstrate that its benefits outweigh its risks would EPA be permitted to review other data, but even then EPA could look only at "[d]ata that tend to show a product does not meet the criteria for registration."

This approach would require EPA scientists to engage in the artificial exercise of "forgetting" what they already know about a pesticide and looking at the data submitted with the application as if no other information existed on the chemical. Such an approach is both unworkable in a practical sense and unacceptable on public policy grounds. The Agency cannot be expected and should not be asked to ignore what it knows -- good, bad, or otherwise -- about particular pesticides. In any event, the Association's proposal would not be a scientifically sound approach to evaluating whether a pesticidally active ingredient would cause unreasonable adverse effects. Universally accepted scientific principles require that decision-makers must take into account all available scientific information in making such determinations. The Association's argument implicitly recognizes this by conceding that EPA may consider all available data to determine whether to deny an application, but not whether to approve a registration. This concession, however, simplistically assumes that an individual test result can be categorized as one which allows registration or one which prevents it. In fact, scientists cannot and properly should not attempt to make such distinctions. Instead, they must weigh all of the known results as a whole, taking into consideration the consistency of the results, the range of variability, methodological differences, and statistical assessments of the results, to determine whether, on balance, the known information justifies a finding that a proposed product is acceptable in risk/benefit terms.

The Association's proposal would also lead to inconsistent results, requiring EPA to register one product but reject an identical product simply because of differences in the outcome of the studies different applicants have provided to the Agency. 9/

9/ EPA recognizes that differences in test results, of course, may be caused by differences in the product or ingredient tested, and the Agency's decisionmaking process will take such (continued)

Moreover, this approach would obviously create strong economic incentives, contrary to the public interest, for an applicant to provide a data set showing as few risks as possible. If the registrability of the applicant's product depends not on its intrinsic safety and efficacy, as demonstrated by the full range of existing data, but rather on the specific results of studies which he submitted or cited, there are powerful incentives to meet this standard. In addition, the proposal would require EPA to devote significantly more resources to making registration decisions (or lessen significantly the number of decisions made per year), because of the redundant and piecemeal reviews of data involved in this approach. Finally, the Association incorrectly interprets the "consider in support" language in §3(c)(1)(D)(i)-(ii) as modifying the §3(c)(5)(C)-(D) risk/benefit criteria. As demonstrated earlier in this Notice, that language is pertinent only to the issue of whether the applicant has met the separate §3(c)((5)(B) criterion by properly -- i.e., as specified by §3(c)(1)(D) -- submitting or citing data sufficient to comply with the §3(c)(2)(A) guidelines. Except for this issue, however, these interim procedures are consistent with the interpretations of FIFRA and the NACA and Monsanto decisions urged in the Association's letter.

PROCEDURES

This portion of this Notice contains five sections. Section I describes the responsibilities of an applicant who relies on the Owner Submission Method to satisfy the Agency's data requirements for registration. Section II details the rights and obligations of data submitters under this system, and section III explains how the Agency will review applications relying on the Owner Submission Method and handle challenges to registrations issued on that basis. Section IV explains that pending applicants must submit additional material in order to rely on this approach, and Section V identifies who to contact for further information.

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differences into account. The Association's proposal, however, goes beyond such valid scientific considerations to argue for limitations on EPA's right to review data not submitted or cited by the applicant, even when the studies are performed on an ingredient in the applicant's product and are clearly relevant to the Agency's risk/benefit determination.

I. Responsibilities Of Applicants

For the Owner Submission Method, the applicant is required to (A) submit a list of data requirements applicable to his product, and (B) satisfy each data requirement either (1) by submitting (or citing) his own valid data, (2) by citing valid data previously submitted to EPA by another, with the original submitter's permission, (3) in certain cases, by documenting that no data have previously been submitted which would meet the specific data requirement, or (4) by a combination of these methods. This procedure is described in parts I.A. and I.B. Part I.C. describes an alternative procedure by which applicants may submit information showing that they have the written permission of all previous submitters of data concerning the product or its active ingredients to rely on that data to support their application. Part I.D. describes an additional procedure by which an applicant may learn whether submitters of exclusive use data have provided data relevant to the applicant's product.

A. Applicant's List of Data Requirements.

Each applicant who uses the Owner Submission Method must prepare and submit with his application a list of the data requirements which he believes are applicable to the product he seeks to register. The list must be based on the Agency's proposed regulations in 40 C.F.R. Part 158, "Data Requirements for Registration," 47 Fed. Reg. 53,192 (November 24, 1982). The method for determining the data requirements for registration is described in proposed 40 C.F.R. §§158.50 and 158.100(b). Applicants seeking to register end-use products should note that the "formulator's exemption" in FIFRA §3(c)(2)(D) may eliminate many data requirements that would otherwise apply. See paragraph A.2., below.

1. Data requirements for registration. Referring to proposed 40 C.F.R. Part 158, the applicant should select the general use pattern(s) (e.g. indoor use, terrestrial non-crop use, aquatic crop use) which best covers the use patterns specified in the proposed labeling of the pesticide product. The nine general use patterns on which most data requirements are based appear as the headings in the tables of data requirements contained in 40 C.F.R. §§158.120 through 158.165. While it will usually be easy to determine which general use pattern(s) would be most appropriate, an applicant may refer to Appendix A of proposed Part 158 for further guidance. Appendix A contains a list of several hundred specific use patterns and the corresponding general use pattern for each.

The applicant should next determine which specific types of studies are required for each of the general use patterns of his product, by referring to each of the tables of data requirements (e.g., §158.120 Product chemistry data requirements, §158.155 Nontarget insect data requirements). The tables indicate for each type of study and general use pattern whether data are usually required, indicated by [R] or R; conditionally required, indicated by [CR] or CR; or not usually required, indicated by a dash (--). The footnotes accompanying each table identify the specific circumstances under which each type of study is required. It is important to read the footnotes for each table.

In some circumstances, an applicant may be unable to determine the applicability of a data requirement because imposition of the requirement depends on the results of other studies which are not known to him. In such a case, the applicant must determine whether such data have previously been submitted to the Agency using the procedure for determining whether a data gap exists (see section I.B.2.). If such data have been submitted previously, the Agency will presume that the data requirement applies to the applicant's product. If such data have not been submitted previously, an applicant for conditional registration will be required to submit the data if EPA determines that the data are needed to make an incremental risk finding under FIFRA §3(c)(7)(B).

2. The "formulator's exemption". The applicant should determine whether he is eligible for the "formulator's exemption" in section 3(c)(2)(D) of FIFRA. Under this section, an applicant for registration of an end-use product is excused from the normal section 3(c)(1)(D) requirement of submitting or citing data on the safety of any ingredient in the applicant's product which is present solely as a result of incorporation into his product (during formulation or packaging) of another product containing that ingredient which is registered under FIFRA and purchased from another producer.

An applicant who wishes to rely on the formulator's exemption must submit with his list of data requirements a fully completed "Formulator's Exemption Statement" (Attachment A). In addition, the applicant must have on file with the Agency a current, complete, and accurate Confidential Statement of Formula (EPA Form 8570-4, Rev. 10-81). The applicant must submit a new Confidential Statement of Formula, unless the one on file with the Agency is current and accurate. Under FIFRA section 12(a)(1)(C), a change in the source of the purchased active ingredient would be unlawful unless the registrant first obtains an amendment to the registration identifying the new source.

3. Waivers. Data required under proposed Part 158 may be waived by EPA under some circumstances. The Agency normally will not require an applicant to satisfy a data requirement that has previously been waived for a pesticide similar to the applicant's product. To facilitate requests for such waivers, EPA will make available, upon request, all lists of data waivers which have been generated for the active ingredients in his product. (This will generally be possible for chemicals for which EPA has established registration standards (52 such standards have been developed to date) and for new active ingredients registered since 1972. The Agency notes, however, that it will not develop such lists where none exists, and that for most products there are no such lists.) An applicant seeking a waiver should indicate on the list of data requirements for his product that a requirement has previously been waived for a similar product, document the existence of the previous waiver, and briefly explain why that waiver should be extended to his product.

During the period in which this interim Owner Submission Method is available, and pending the development of final regulations, the Agency will only consider requests for new waivers when the applicant would actually be required to generate data in order to obtain registration. Thus, for example, an applicant for registration of a new use of a currently registered product may request that EPA waive some or all of the data pertaining to the new use. EPA does not expect to issue many waivers of this kind.

4. Form of the list. Each type of data requirement on the applicant's list shall be identified by the description contained in the columns headed "Kind of data required" and listed in the same order as they appear in proposed Part 158. Each list of data requirements shall include a subheading for each group of studies listed in a separate table of data requirements (e.g., toxicity studies, environmental fate studies). Finally, the list shall indicate how the applicant is satisfying each data requirement.

B. Satisfying the Data Requirements.

An applicant may satisfy a data requirement: (1) by submitting valid data or by citing valid data previously submitted by the applicant; (2) by citing valid data previously submitted by another person, with the original data submitter's permission; (3) in certain cases, by showing that a "data gap" exists; or (4) by a combination of these methods.

1. Submitting and citing data. Applicants must identify on each submission of data which portions (if any) should be treated as trade secret or confidential business information. Applicants must also indicate whether data submitted with the application have or have not previously been provided to the Agency by the applicant. The Agency prefers that previously submitted data not be resubmitted. Rather, such data should be cited with the following information:

a. Where available, EPA's Master Record Identification (MRID) Number; 10/ if no MRID number is available, EPA's data catalogue accession number (if known);

b. The original submitter's identity;

c. If the data being cited were originally submitted by a person other than the applicant, evidence that all rights to the data have been permanently transferred to the applicant or a written statement signed by an authorized representative of the original data submitter giving the applicant permission to cite the data;

d. The date on which the cited data were originally submitted; and

e. The title or other adequate description of the study (e.g., "Study of the acute oral toxicity of [product name] to Norway rats").

2. Data gaps. An applicant for conditional registration may wish to demonstrate that a data gap exists for a particular data requirement -- i.e., that no one has previously provided such data to the Agency -- and that under the conditional registration provisions of FIFRA §3(c)(7), registration would be proper notwithstanding the data gap. (If EPA needs the data to perform an incremental risk assessment, EPA will require submission of the data. See FIFRA §3(c)(7)(B).) If an applicant wishes to claim that a data gap exists, he shall certify that

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10/ The EPA is currently preparing a computerized index of each study and set of data submitted to the Agency. The public may obtain the indexed information, including the MRID number and certain other identifying information on any indexed study, by filing a Freedom of Information Act request with the Agency. The process of indexing and assigning MRID numbers is scheduled to be completed in 1984.

he has no basis for believing that data meeting the data requirement have been submitted by any other person. He shall also certify that he has provided notice by certified mail, return receipt requested, to every person appearing on the List of Data Submitters for each active ingredient in his product for which he claims a data gap exists. 11/ The notice shall include:

a. A statement that the applicant intends to apply for registration or amended registration of a pesticide under FIFRA §3(c)(7) using the Owner Submission Method described in this notice, and that he intends to claim to be excused from the requirement of submitting certain data because of the existence of data gaps, as allowed by this Notice;

b. A list of the data requirements (by type of study and test substance) for which the applicant intends to claim that a data gap exists;

c. A request that, within 60 days of receipt, the data submitter identify, in the manner specified in this Notice, each valid study that the data submitter has previously submitted to EPA (or to its predecessors) and that would satisfy any of the requirements the applicant has listed.

If the Agency issues a registration on the assumption that a data gap exists for a particular data requirement, and if it is subsequently determined that valid data had been submitted concerning that requirement of which the applicant had been notified in a timely manner, the procedures specified in section III.E., below, shall apply to such registration.

C. Permission of All Prior Data Submitters

As an alternative to the procedure described in Part I.A. and I.B., an applicant may satisfy the Agency's minimum data requirements by providing information showing that he has permission to rely on all data relevant to his product which have previously been submitted to EPA. The applicant must provide a letter, or other appropriate documentation, signed by an authorized representative of each prior data submitter giving the applicant the right to cite any such data that the data submitter has provided to EPA. The applicant must obtain such permission from everyone appearing on the Agency's most recent list of "Pesticide Data Submitters by Chemical" and any other person identified by EPA as a prior submitter of such data.

11/ In the event that the notice cannot be delivered to a data submitter, the applicant shall describe the efforts which were made to provide notice.

D. Notice to Prior Data Submitters

An applicant may send a certified letter, return receipt requested, to submitters of exclusive use data 12/ pertaining to an ingredient in the applicant's product notifying them that the applicant seeks to register a pesticide intended for specified uses and containing specific active ingredients on which the submitters have previously submitted data. A recipient of such a letter shall have 60 days in which to transmit to the applicant a list of the data which the data submitter believes are required for such a product. In addition, a data submitter may choose to send a copy of this list to EPA.

If a data submitter fails to make a timely response to the applicant, the data submitter will be presumed to have waived certain of his rights to challenge registration of the applicant's product. Specifically, where a list of data requirements is requested by the applicant, the data submitter may not challenge the applicant's failure to list a requirement that was not contained on the responsive list of data requirements prepared for the applicant's product by the data submitter until after the application has been approved. This section does not limit a data submitter's right to challenge a registration action after the Agency has issued the registration.

The presumption that the data submitter has waived his rights to challenge a registration may be overcome by a showing that there was good cause for the data submitter's failure to respond in a timely manner and that the data submitter responded as promptly as possible under the circumstances.

II. Rights And Obligations Of Data Submitters

A. Responding to "Data Gap" Letters.

As explained in section I.B.2, applicants are required to contact all original data submitters if they wish to claim that a data gap exists. Data submitters are not required to respond

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12/ "Exclusive use data" means data which would be covered by FIFRA § 3(c)(1)(D)(i), if that section were operative.

to these notices. However, if a data submitter fails to respond within 60 days, he may have waived his right to contest an applicant's claim that a data gap exists. The Agency will presume that no data satisfying a particular requirement exist if the applicant states in his application that:

(1) he has furnished notice as described in paragraph I.B.2. of this Notice identifying the alleged data gap, and

(2) that no data submitter has informed the applicant in writing within 60 days that he has submitted valid data satisying the requirement.

This presumption may be overcome only if the data submitter shows good cause for the failure to provide timely notice to the applicant and acts promptly to provide such notice once it becomes possible. A data submitter cannot overcome this presumption merely by providing notice to EPA (but not to the applicant) that data satisfying a particular data requirement have previously been submitted to EPA.

The Agency notes that an applicant relying on the Owner Submission Method may cite another person's data only if the original data submitter has given his permission. The data submitter is not required to give his permission and does not do so merely by responding to a "data gap" letter.

B. Supplying Lists of Data Requirements and Submitted Data.

A data submitter may supply to the Agency a list of what he believes to be the data requirements for a particular kind of product. A data submitter may also supply to the Agency a list of applicable, valid data that he has submitted on any particular active ingredient. Any such list shall be made available to the public on request, to the extent permitted by law. As described in sections III.A. and B., EPA will review such submissions by original data submitters in determining whether applicants have complied with this Notice.

C. Notification of Applications Involving "Exclusive Use" Data.

An original data submitter who has provided EPA with information on an active ingredient that would be subject to "exclusive use" under FIFRA §3(c)(1)(D)(i) will be notified by EPA of each application for registration of a product containing

that active ingredient at least 30 days before the registration is approved. 13/

III. Agency Review Of Applications Using The Owner Submission Method

EPA will review applications relying on the Owner Submission Method to determine whether (A) the applicant has listed all data requirements applicable to his product; (B) the applicant has satisfied each data requirement by using one of the methods listed in section I.B.; (C) the "new" data submitted by the applicant are valid; (D) the applicant generated, has all relevant rights to, or has permission to rely on, all data submitted or cited; and (E) the applicant's product meets the standards for registration in FIFRA section 3(c)(5) or 3(c)(7). In addition, EPA will review challenges to decisions to register a product as provided in paragraph E of this section.

A. Review Of An Applicant's Data Requirements List.

EPA will review the list of data requirements submitted by an applicant to determine whether all applicable requirements have been identified. Where a data submitter has supplied a list of requirements to EPA, the Agency will compare this list with the applicant's list of data requirements. In addition, in case of conflict between applicants and previous data submitters which cannot be resolved by other means, EPA may review the studies in its files to determine whether the data would lead to the imposition of any additional conditional data requirements not listed by the applicant.

13/ In response to concerns expressed by some firms about the meaning of statutory provisions governing consideration of previously submitted data, during the period in which this Notice is in effect EPA will, at the request of any applicant for registration of a product containing any active ingredient on which another person has previously submitted data entitled to exclusive use protection under §3(c)(1)(D)(i), or at the request of any such previous data submitter, voluntarily attempt to evaluate the risks, benefits, and registrability of the applicant's product based solely upon the data submitted or cited with the application. The Agency's conclusions about the registrability of such a product on that basis will be made available to the applicant and the original data submitter as part of the 30-day notice set forth in this paragraph II.C. The actual registration decision for any such product will be based on the procedures described in this Notice for all products.

If the Agency concludes that an applicant has failed to list an applicable data requirement, the Agency will refuse to register the product and will promptly notify the applicant of its determination. The Agency notes, however, that approval of a registration does not represent a waiver of any applicable data requirement not listed by the applicant.

B. Review of Applicants' Data Submissions.

As noted in section I.B., the Agency requests that applicants submit only those data which have not previously been provided to the Agency. EPA will conduct an independent scientific review of all major tests which are being supplied to the Agency for the first time to determine whether they are valid (i.e., whether they supply scientifically useful information), and whether they fulfill an Agency data requirement (i.e., whether the data provide sufficient information to permit EPA to adequately assess a particular property of the pesticide on which data are required, such as its teratogenicity or persistence). The Agency also will determine whether the results of any newly submitted tests alter any prior regulatory judgments it may have reached about the registrability of products such as the applicant's. 14/

The Agency will not necessarily review data submitted or cited by the applicant which have previously been submitted to the Agency, and approval of a registration does not constitute a finding by the Agency that such studies are valid. If, however, the Agency determines that data submitted or cited by an applicant are not valid or do not fulfill the requirements for which they were submitted or cited, the Agency will refuse to register the product and will promptly notify the applicant of its conclusion.

In addition, where a data submitter supplies a list of data that he has submitted to the Agency, EPA will attempt to ensure that the applicant is not relying on such data without permission, and has not improperly claimed a data gap to exist.

14/ EPA also will continue its present practice of attempting to determine whether differences in test results are attributable to differences in composition of the substances tested and, if they are, of evaluating the regulatory significance of those composition differences.

C. Review of Applications for Registration.

1. Approval of routine applications. If the Agency determines that the applicant has supported its application adequately (i.e., has listed and satisfied each applicable data requirement as specified in this Notice), the Agency will then determine whether the product meets the other standards for registration in FIFRA §3(c)(5) or §3(c)(7). The Agency will perform as extensive a review as necessary to determine whether the application meets those statutory standards, and the Agency will not limit its review of data solely to those studies submitted or cited by the applicant. Except as provided below, EPA will issue registrations for any pesticide product as soon as it determines that the product is acceptable.

2. Additional procedures for registrations raising "exclusive use" concerns. If a product acceptable for registration contains an active ingredient for which data subject to exclusive-use protection have been submitted to the Agency, the Agency will notify all persons who have submitted data on that ingredient of the proposed action. Specifically, thirty days prior to approval of such an application, EPA will notify the applicant and original data submitters of the proposed registration and of the Agency's decision on any points as to which there was a disparity between the application materials and any lists of data or data requirements provided by the original data submitters.

D. Public Availability of Owner Submission Materials.

The Agency will also rely on data submitters to monitor compliance with the procedures and requirements for registration. In this regard, the Agency will periodically make available to the public a list of applications which have been approved, including:

(1) the registrant's name and address;
(2) the product's name and registration number;
(3) the date of registration;
(4) the active ingredient(s) in the product; and
(5) the method of support used.

On request, following approval of an application, the Agency will make available, to the extent legally permitted, an applicant's list of data requirements and list of submissions purporting to satisfy each data requirement.

E. Review of Challenges to Registration Actions Based on the Owner Submission Method

Any data submitter who is adversely affected by the issuance of a registration on the ground that the application (or EPA's approval of it) failed to comply with this Notice may file a written petition with the Agency requesting that EPA cancel the registration of the product. The petition should state that the petitioner has previously submitted to EPA data which would fulfill each data requirement the petitioner claims the applicant has failed to satisfy. The petition should also describe the manner in which the applicant has failed to satisfy the data requirements for the product. The grounds for such a petition could include:

(1) the applicant has failed to list a data requirement applicable to his product, or to satisfy all applicable data requirements;

(2) the applicant has submitted or cited a study that is not valid or that does not fulfill the data requirement in connection with which it was submitted;

(3) the applicant has failed to comply with the procedures for showing that a data gap exists, or has improperly represented that a data gap exists; or

(4) the applicant has, without permission, submitted or cited a study which is not his own.

EPA will furnish a copy of the petition to the registrant in question. The Agency will consider written comments responding to the petition submitted within 60 days after the date on which the petition is received by the registrant.

EPA will review petitions and any comments on them to determine whether they present a substantial basis for arguing that the registration of a pesticide should be cancelled. If EPA determines that a petition is without merit, it will deny the petition. If, on the other hand, the Agency concludes that a petitioner has shown a possible violation of the registration procedures and that such a violation may have deprived the petitioner of legal rights involving previously submitted data, EPA will issue either a Notice of Intent to Cancel Registration under FIFRA §6(b)(1) or a Notice of Intent to Hold a Hearing under §6(b)(2) of FIFRA. 15/ The purpose of such a

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15/ Prior to issuing such a Notice, EPA may inform the registrant and petitioner of its preliminary assessment and allow a brief period during which efforts can be made to resolve the matter informally.

hearing will be to determine whether the claims made in the petition are true, and if so, whether the registrant failed to satisfy the requirements of this Notice. Any such hearing will be conducted under the procedures described in EPA's Rules of Practice, 40 C.F.R. Part 164. At the conclusion of a hearing, if the Agency determines that an applicant failed to comply with the requirements of this Notice, EPA will cancel the registration which was based on that application.

IV. Effect on Pending Applications

All persons with applications for registration actions pending before the Agency must resubmit or modify those applications as necessary to comply with this Notice, unless the applications are for those actions not involving consideration of data as identified in 40 C.F.R. 162.9-1(b).

V. Further Information

If you wish additional information on this Notice, please contact either an appropriate Product Manager in the Registration Division or Herbert S. Harrison at (703) 557-2200.

Edwin L. Johnson, Director
Office of Pesticide Programs